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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,122	08/16/2001	Tony Baker	24219-001CIP2	4239

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/932,122	**Applicant(s)** BAKER, TONY	
	Examiner Jehanne S. Sitton	**Art Unit** 1634	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 January 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *30 January 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attachment*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1-49*.
   Claim(s) withdrawn from consideration: *NA*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Attachment

1. The amendment filed 1/30/2006 will not be entered because it changes the scope of the claims and raises new issues that would require further search and consideration. Specifically, the proposed amendment filed 1/30/2006, has changed the scope of claims 1-49. The proposed amendment to independent claim 37 provides for a method of improving hybridization of nucleic acids by suppressing a masking agent selected from a group of masking agents consisting of leukocyte esterases, myoglobin and hemoglobin analogues, myoglobin and hemoglobin derivatives, myoglobin and hemoglobin oxidation products, myoglobin and hemoglobin breakdown products, ferritins, methemoglobin, sulfhemoglobin, and bilirubin. Further, independent claims 1 and 17 were also amended to list the particular group of masking agents set forth above. Such proposed amendments would require further search and consideration because they add new limitations to the claims which the previous claims were not limited. With respect to claims 1 and 17, the added limitation of "myoglobin and hemoglobin derivatives" was not present in any of the claims. With respect to independent claim 37, and claims which depend therefrom, no previous claims were drawn to a method of improving hybridization by suppressing a masking agent, and more particularly, the previous set of claims did not provide for any limitations of improving hybridization by suppressing leukocyte esterases, myoglobin and hemoglobin analogues, myoglobin and hemoglobin derivatives, myoglobin and hemoglobin oxidation products, myoglobin and hemoglobin breakdown products, ferritins, methemoglobin, sulfhemoglobin, or bilirubin, as proposed claim 37 and the claims which depend therefrom are now limited. Therefore, such amendments raise new issues and require a new search. Additionally, the amendment to claims 1 and 17 requires further search and consideration for

claims which depend therefrom as the majority of these dependent claims did not require suppression of the specific masking agents listed above. Accordingly, the amendment has provided for limitations to a large number of claims which were not present before and must be searched and reconsidered.

2. The response traverses the rejection made in the final rejection of claims 1-8, 14, 15, 17-24, 30, 36-43, 45, 46, and 48 under 35 USC 102(b) as being anticipated by Chung et al. The response asserts that there is no discussion of any of the masking agents contemplated in the present application and that the extraction of RNA from samples of pulverized sesame or perilla oilseeds does not inherently involve freeing the RNA from masking agents of the type recited in claim 1. This argument has been thoroughly reviewed. Arguments directed to the proposed amendment of claim 1 submitted 1/30/2006 will not be addressed as they do not apply to the claims as are instantly pending. With regard to the arguments that Chung does not discuss suppression of masking agents "contemplated in the instant application", applicant is reminded In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., masking agents recited in claims 10-13, and 26-29) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). At page 5, the specification defines a masking agent or interferent of a molecular assay as including compounds which interfere or otherwise affect the accuracy of the assay, masking the true or detectable

amount of the nucleic acid in the sample. The specification's recitation of leukocyte esterases, heme proteins, etc, are examples of masking agents, they do not provide an express definition of a masking agent and therefore are not read into the claims. Claims 10-13 and 26-29, which recite these specific masking agents, were not included in this rejection. Further, the specification provides no express definition of a molecular assay and instead states that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), hybridization assays (page 3), probe based diagnostics, microarray/Chip methods, PCR, amplification, SNP analysis, DNA sequencing, drug discovery, drug response genes, (page 4, lines 19-22), NASBA, SDA, and genetic transformation testing (page 5). As such, no specific definition is given. Instead, the specification provides very broad and general teachings of molecular assays, and therefore the term "molecular assay" can be broadly and reasonably interpreted to be any assay involving nucleic acids. Therefore, the recitations of the instant broadly recited pending claims do not distinguish over the teachings of Chung.

The response asserts that Chung does not disclose 'suppressing the interference of a masking agent of a molecular assay of a nucleic acid containing test sample'. This argument has been thoroughly reviewed but was not found persuasive as the claims do not recite any specific suppression, nor does the specification provide any definition for such term. Therefore, the term's broadest reasonable interpretation is the removal of such interference, in any manner, such that the interference or masking is no longer there. The response further asserts the assay for DNA purity (A_{260}/A_{280} determination) taught by Chung, cannot by itself be taken to indicate suppression of interference from a potential masking agent as many masking agents are non protein and do not necessarily absorb ultraviolet light in the relevant wavelength and may still be

present. This argument has been thoroughly reviewed but was found unpersuasive because the claim does not require the suppression of all possible masking agents. Additionally, Chung specifically teaches that the quality of RNA was dependent on the RNA extraction buffer used and that buffer A greatly enhanced the RNA quality isolated from oilseeds of sesame and perilla (p. 110, col. 1, lines 1-4). Chung teaches assessing the quality and quantity of extracted RNA, Northern Hybridization (fig 2), and RT-PCR with the RNA (conducting a molecular assay on the extracted molecular analytes of interest). Table 1 of Chung teaches enhanced absorbance ratios (improved signal response) and Figure 1 of Chung teaches clearer bands on an agarose gel with the use of buffer A. Claims 36 and 48 are drawn to the method wherein the molecular assay is PCR. Chung teaches constructing cDNA libraries from RNA populations acquired using buffer A, and that northern hybridization using cDNA probes showed that the RNA isolated was intact and functional (page 111- first para, figure 2), therefore Chung inherently teaches an RT-PCR method with improved signal (figure 2) (in this case, "signal response" is broadly interpreted to encompass intact and functional cDNA derived from isolated RNA using buffer A). The response asserts that there is no teaching in Chung of improving hybridization of nucleic acids and that the demonstration of intact and functional cDNA does not necessarily and inevitably lead to the conclusion that hybridization has improved. This argument has been thoroughly reviewed but was found unpersuasive. Chung specifically teaches that high quality RNA is essential for Northern hybridization (see page 108, col. 1, first sentence), and that polysaccharide contaminated RNA compositions are not suitable for such molecular procedures. Chung teaches a buffer composition (buffer A) that allowed for high quality RNA isolation, and teaches that

specifically given the results of a northern hybridization assay (figure 2), the RNA obtained using buffer A was assumed to be intact and functional.

The response additionally asserts that it is inappropriately broad to consider the term "molecular assay" to be "any assay involving DNA" as suggested by the office action because it is clear from the examples given at lines 17-22 of page 5 of the specification that "molecular assay" is intended to include only assays in where there is sequence-specific recognition of nucleic acids by a protein or another nucleic acid and that therefore a simple assay of the quantity of DNA by measurement of A-280 would not be properly construed as a molecular assay in light of the specification. This argument has been thoroughly reviewed but was found unpersuasive. The examples listed at lines 17-22 of page 5 of the specification provide for examples of molecular assays. They are not an express definition of what constitutes a molecular assay and in fact, with the recitation of "includes", set forth that the genus of "molecular assay" is broader than the assays recited therein. The specific examples of molecular assays represent limitations set forth in the specification and cannot be read into the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims have been read in light of the specification, which teaches that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), drug discovery and drug response genes, pharmacogenomics (page 4, lines 19-22) which are not limited to "sequence specific recognition of the DNA either by a protein or by another nucleic acid". The specification provides for a broad discussion f DNA analysis, and thus the claims

have been read in light of such broad teachings. For these reasons and the reasons already made of record, the rejection is maintained.

3. The response traverses the rejection made in the final rejection of claims 1-6, 8-9, 14-22, 24-25, 31-41, 43-44, and 46-48 under 35 USC 102(b) as anticipated by Sigman et al.

The response asserts that Sigman et al does not recite specifically the masking agents in the claims as amended. This argument as well as other arguments pertaining to the proposed amended claims will not be addressed as they does not pertain to the instantly pending claims. The response asserts that Sigman does not specifically disclose the interference of a masking agent and that any suppression of interference is unintentional and inadvertent and therefore cannot anticipate the claimed invention. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use. Therefore, the suppression of interference by a masking agent, such as nuclease, was not inadvertent or unintentional. Sigman, at page 3, specifically teaches use of a buffer containing the claimed components to preserve the DNA from degradation. Secondly, as stated in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference."

The response's assertion that the term "molecular assay", in light of the specification, must be read to mean an assay in which sequence specific recognition plays some role is not found persuasive. Sigman does teach assays in which sequence specific recognition plays a role (PCR). Further, the specification provides no express definition of a molecular assay and

instead states that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), hybridization assays (page 3), probe based diagnostics, microarray/Chip methods, PCR, amplification, SNP analysis, DNA sequencing, drug discovery, drug response genes, (page 4, lines 19-22), NASBA, SDA, and genetic transformation testing (page 5). As such, no specific definition is given. Instead, the specification provides very broad and general teachings of molecular assays, and therefore the term "molecular assay" can be broadly and reasonably interpreted to be any assay involving DNA.

The response's arguments that the "mere preservation for future use does not in and of itself establish that the DNA is preserved in a condition in which the specific masking agents recited in the claims of the present application are eliminated or suppressed" will not be considered because they are not directed to the instantly pending claims.

The response also asserts that prevention of degradation by a nuclease cannot be equated with suppression of interference of a masking agent because most masking agents do not act to degrade DNA. This argument has been thoroughly reviewed but was found unpersuasive. The specification defines a masking agent as "compounds which interfere or otherwise affect the accuracy of an assay, masking the true or detectable amount of the nucleic acid in the sample". The presence of a nuclease which would degrade a nucleic acid in a sample which contains nucleic acid, would mask the true or detectable amount of nucleic acid in the sample. The fact that many masking agents are not nucleases does not change the property of the nuclease. The specification does not exclude nucleases as masking agents. The response's interpretation of "suppression of interference with a masking agent" represents further invention after the time of filing, which is not basis for withdrawal of the rejection.

The response's assertion that Sigman does not teach or disclose improvement in hybridization because Sigman focuses on methods by which DNA is subject to chemical cleavage and that anticipation is unintended and accidental is not found persuasive. As already noted above, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use, such as PCR - which uses hybridization. Therefore, the suppression of interference by a masking agent, such as nuclease, was not inadvertent or unintentional. Sigman, at page 3, specifically teaches use of a buffer containing the claimed components to preserve the DNA from degradation. Also, as stated in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." Arguments that Sigman does not teach improvement in hybridization that can be attributed to the removal or suppression of the masking agents recited in the claims will not be addressed as they do not pertain to the instantly pending claims.

4. The response traverses the rejection made in the final rejection of claims 1-6, 8-9, 15-16, 37-41, and 43-47 under 35 USC 102(b) as anticipated by Zhang. The response arguments are directed to the proposed amendments to claims 1-6, 8-9, 14-16, 37-41 and 43-47 to specifically recite the list of masking agents noted above. Such arguments will not be addressed as they do not pertain to the instantly pending claims.

5. The response traverses the rejection made in the final rejection of claims 1-3, 6, 10-19, 22, 26-32, and 34-36 under 35 USC 102(e) as anticipated by Harvey et al as defined by Akane et

al. [It is noted that in the first office action and applicant's responses contain a typographical error and refer to the parent application as 09/185,401 or '401 (09/185,*402* is the correct number). For the purposes of providing a clear record, this typographical error was corrected in the final rejection and in the instant advisory action. It is noted that the response continues to incorrectly refer to the application as '401]

The response asserts that there is no basis for the position taken by the office that the '402 application does not provide support for the recitation of a masking agent in general. The response asserts that hemoglobin and methemoglobin are typical masking agents and that it is well understood that not all specific examples of a compound that has a particular activity or properties be recited in the specification for there to be support for a more general recitation of a compound having such activity or properties. This argument has been thoroughly reviewed but was found unpersuasive. The MPEP at 2163.03, II, states "Under 35 USC 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed US application if the subject matter of the claim is disclosed in the manner provided by 35 USC 112, first paragraph in the earlier filed application". Additionally, the MPEP at section 2163.05, states "... in *Tronzo v. Biomet*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application. Similarly, see *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds). The '402 application does not recite the broad generic term

"masking agent", nor does it provide support for "suppressing a masking agent" or suppressing the interference of a masking agent, or such masking agents as leukocyte esterases, and bilirubin. As is exemplified by the definition in the instant specification, a masking agent is defined at page 5 as "compounds which *interfere* or otherwise *affect the accuracy* of the assay, masking the true or detectable amount of nucleic acid in the sample", which can include other proteins than the heme containing proteins hemoglobin and methemoglobin, as well as other types of molecules such as carbohydrates, nucleic acids, etc. The previous response dated 5/2/05, at page 17, states that many masking agents are non protein. The term encompasses a large genus of structurally and functionally distinct molecules, which are not represented either structurally or functionally by hemoglobin or methemoglobin. The term "masking agent" and suppression of any "masking agent" or suppression of the interference of any "masking agent" thus represents a broadening of the invention in the '402 application and does not find support in the '402 application under the written description requirement of 35 USC 112, first paragraph.

The response further asserts that Harvey does not teach the claimed invention because Harvey does not teach adding the required components to a test sample as is used in the specification and the claims because the nucleic acid is applied to absorbent paper and that the nucleic acid must be released from the support to create a test sample. This argument has been thoroughly reviewed but was found unpersuasive. The instant specification does not provide a specific definition for a "test sample" but the term "sample" is defined as substances containing or presumed to contain nucleic acid, including bodily fluids (page 6). Further, the instantly rejected claims simply recite that the test sample is contacted with an amount of a divalent metal chelator (dependent claims include EDTA) and a chelator enhancing component (dependent

claims include guanidine), which is taught by Harvey (see example 6, blood – test sample containing nucleic aid- is collected in a tube containing EDTA –divalent metal chelator- and a square containing guanidine –chelator enhancing component- is added). Therefore, Harvey specifically teaches contacting a test sample with a chelator and chelator enhancing component and anticipates the instantly pending claims. The response's assertion that "A sample of nucleic acid absorbed on filter paper, as is disclosed by Harvey et al is not a test sample and cannot be used for that purpose" is not understood. The response does not provide any explanation for the limited interpretation of "test sample", nor does the specification provide any express definition of "test sample" to provide for such limited interpretation. The instantly rejected claims simply recite that the test sample is contacted with an amount of a divalent metal chelator (dependent claims include EDTA) and a chelator enhancing component (dependent claims include guanidine), which is taught by Harvey. At example 6, Harvey teaches a test sample containing nucleic acid which is blood. Harvey teaches that the test sample is collected in a tube containing EDTA –divalent metal chelator, and therefore teaches contacting the test sample with an amount of a divalent metal chelator. Harvey teaches that a square containing guanidine –chelator enhancing component- is added, and therefor also teaches contacting the test sample with a chelator enhancing component. Therefore, Harvey teaches contacting a test sample with both a divalent metal chelator and a chelator enhancing component and clearly anticipates the claimed invention. For these reasons and the reasons already made of record, the rejection is maintained.

6. The response traverses the rejection made in the final rejection of claims 7 and 23 under 35 USC 103(a) as obvious over Harvey et al. The response asserts that all claim limitations must

be considered in evaluating non-obviousness of an invention in light of the prior art and that as indicated previously, Harvey does not teach the use of the agents taught by Harvey in a test sample. This argument has been thoroughly reviewed but was not found persuasive for the reasons made of record above. As noted previously, the instantly rejected claims simply recite that the test sample is contacted with an amount of a divalent metal chelator (dependent claims include EDTA) and a chelator enhancing component (dependent claims include guanidine), which is taught by Harvey. At example 6, Harvey teaches a test sample containing nucleic acid which is blood. Harvey teaches that the test sample is collected in a tube containing EDTA – divalent metal chelator, and therefore teaches contacting the test sample with an amount of a divalent metal chelator. Harvey teaches that a square containing a chaotropic agent - chelator enhancing component- is added, and therefor also teaches contacting the test sample with a chelator enhancing component. Harvey teaches a method whereby a test sample containing nucleic aid- is collected in a tube containing EDTA –divalent metal chelator- and a square containing a chaotropic agent –chelator enhancing component- is added. Although Harvey does not specifically exemplify 903 paper with sodium perchlorate, Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as sodium perchlorate. All the specification requires of a "sample" as expressly defined at page 6, is that it includes substances containing or presumed to contain nucleic acid, and includes for example, blood cells. This is taught by Harvey. For these reasons and the reasons already made of record, the rejection is maintained.

7. The response traverses the rejection made in the final rejection, of claim 49 under 35 US 103 as unpatentable over Chung or Sigman or Harvey in view of Ahern. The response also traverses the rejections in the final rejection made under Obviousness type double patenting of claim 49 over claims 1-8 of the '546 patent in view of Ahern, of claim 49 over claim 19 of the '543 application, and of claim 49 over claims 17-18 of the '543 application in view of Ahern. All the arguments are directed to the proposed amendment to claim 49 to add specific masking agents and therefore will not be addressed as they do not pertain to the instantly pending claims.

8. The response traverses the rejections made in the final rejection of claims 1-16 under Obviousness type double patenting over claims 1-8 of the '546 patent, and claims 17-36 and 48 over claims 1-8 of the '546 patent in view of Sigman. Arguments directed to the amendment to claim 1 and 17 will not be addressed as they do not pertain to the instantly pending claims. The response asserts in both cases that the claims of the '546 patent do not recite a method of suppressing the interference of a masking agent and that preservation of a sample cannot necessarily be equated with suppression of interference by a masking agent [or improved signal response in a molecular assay by suppression of a masking agent]. With regard to claims 17-36 and 48, the response additionally asserts that Sigman does not teach suppression of interference by a masking agent or improved signal response in a molecular assay by suppression of a masking agent. These arguments have been thoroughly reviewed but were not found persuasive. Firstly, while there can be many purposes for preserving a sample and a sample can be preserved even though masking agents remain, in the instant case, the method steps used in each method are coextensive in scope. The claimed method steps of the instant application encompass the

more narrow methods steps of the claims of the '546 patent. The instantly claimed invention encompasses addition of an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid containing nucleic acid. Claim 1 of the '546 patent is drawn to adding an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid to. It is further noted that instant dependent claims 4 and 8 are drawn to concentrations that are recited in the preservative solution of claim 1 of the '546 patent. As guanidine isothocyanate is a chaotropic agent which would inhibit nucleases, the suppression of a masking agent is considered a property of the claimed method of the '546 patent, as exemplified by the teachings of '546 that the invention "has been found to surprisingly modulate the effect of hemoglobin, e.g., methemoglobin, interference on nucleic acid assays such as PCR..." (for claims 1-13 and 26-29, which specifically encompass hemoglobin or methemoglobin). Thus, the claims are coextensive in scope and not patentably distinct from each other. For these reasons and reasons already made of record, the rejections are maintained.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634
2/9/06